

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ZOLOFT (SERTRALINE  
HYDROCHLORIDE) PRODUCTS  
LIABILITY LITIGATION**

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***THIS DOCUMENT RELATES TO ALL  
ACTIONS***

§ **MDL NO. 2342**  
§  
§ **12-MD-2342**  
§  
§ **HON. CYNTHIA M. RUFÉ**  
§

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR  
MOTION FOR SUMMARY JUDGMENT**

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Defendants respectfully submit this memorandum of law in support of their motion for summary judgment under the Court's "standard approach" for summary judgment (Hon. Cynthia Rufe's Policies & Procedure, at 4).

### **PRELIMINARY STATEMENT**

Defendants are entitled to summary judgment in all cases in this MDL because the *Daubert* process for all of Plaintiffs' general causation experts has been completed and the Court has excluded as unreliable the testimony of Plaintiffs' experts on general causation in humans. (Dkt. [979], [980], [1033], [1034].) Plaintiffs thus lack admissible and sufficient evidence necessary to establish an essential element of their claims: causation. Plaintiffs admit that "[p]roof of general causation – that exposure to Zolofit was capable of causing plaintiffs' injuries – is a prerequisite to recovery by every plaintiff herein." Pls.' Br. (Dkt. [1054-1]) at 13. Without admissible and sufficient evidence to establish this essential element of their claims, Plaintiffs' claims fail as a matter of law. Accordingly, courts routinely hold that where plaintiffs' evidence of general causation is excluded, summary judgment must follow, including in MDL cases.

### **ARGUMENT**

#### **I. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT BECAUSE PLAINTIFFS LACK ADMISSIBLE AND SUFFICIENT EVIDENCE OF GENERAL CAUSATION**

More than two decades ago in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court held that "in the event the trial court concludes that the ... evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free ... to grant summary judgment" under Rule 56. 509 U.S. 579, 596 (1993). Since then, litigants and courts alike have recognized that the exclusion of essential expert evidence under *Daubert* routinely leads to summary judgment. Indeed, once expert causation opinions have been excluded, the question whether summary judgment is warranted under Rule 56 "becomes academic." *Raskin v. Wyatt Co.*, 125 F.3d 55, 67 (2d Cir. 1997) (quoting *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir. 1991) (en

banc)). There can be no doubt that, under the framework of the Federal Rules of Evidence and Federal Rules of Civil Procedure, if general causation experts are excluded under *Daubert*, summary judgment necessarily follows.

**A. This MDL Court Has the Power to Enter Summary Judgment in All Cases**

Third Circuit law, the *Multidistrict Litigation Manual*, and the Federal Judicial Center all make clear that this Court, as the transferee court in an MDL, has the power under 28 U.S.C. § 1407 to dispose of all cases on summary judgment and should do so where, as here, the plaintiffs have failed to provide admissible and sufficient evidence to prove an essential element of their claims: causation. Simply put, an MDL court has the same responsibility as any other court to dismiss cases on summary judgment where the plaintiffs have failed to prove an essential element of their claims. That is particularly true where, as here, the impetus for summary judgment are *Daubert* general causation decisions that foreclose “a prerequisite to recovery by *every* plaintiff herein.” Pls.’ Br. at 13 (emphasis added).

MDL courts consistently recognize the appropriateness of deciding cases on summary judgment. As Judge Becker explained in *In re Donald J. Trump Casino Secs. Litig.-Taj Mahal Litig.*, 7 F.3d 357 (3d Cir. 1993), “we take this opportunity to make clear that § 1407 empowers transferee courts to enter a dispositive pretrial order terminating a case.” *Id.* at 367. Further, “transferee courts frequently terminate consolidated cases in practice.” *Id.*; see also *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006); *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996). “In practice ... the vast majority of transferred cases are disposed of completely in the transferee court, either through pretrial dispositions such as summary judgment, or by trial.” *In re Food Lion Inc., Fair Labor Standards Act Litig.*, 73 F.3d 528, 532 (4th Cir. 1996).

Citing the Third Circuit’s decision in *Trump*, the *Multidistrict Litigation Manual* also recognizes that MDL courts “have the clear power” to “dispose[] of entire cases” on “motions for summary judgment under Rule 56.” David F. Herr, *Multidistrict Lit. Man.* § 9:21 (2014). With respect to products liability MDLs in particular, the Federal Judicial Center’s guidebook



recognizes that MDL courts “may terminate ... all actions in the MDL docket by ruling on motions ... for summary judgment.” Federal Judicial Center, *Managing Multidistrict Litig. in Products Liability Cases*, at 4 (2011).

MDL courts in the specific context of products liability litigation have disposed of hundreds of cases at once with a single pre-trial ruling. In *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 2014 WL 2011239 (E.D. Pa. 2014) (Rufe, J.), this Court granted summary judgment to the defendant in 115 cases. In *In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, 2014 WL 1266994, at \*1 (D.N.J. 2014),<sup>1</sup> a litigation involving a prescription medicine that allegedly caused bone fractures, the MDL court granted judgment as a matter of law to the defendant in over 650 cases. In *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 718618, at \*6 (E.D. Ky. 2012), *aff’d*, 2014 WL 2959271 (6th Cir. 2014), a litigation involving a medicine that the FDA withdrew from the market and that the plaintiffs alleged caused cardiac injuries, the MDL court dismissed with prejudice more than 600 cases.<sup>2</sup> In *In re Neurontin Prods. Liab. Litig.*, 2011 WL 1326407, at \*7 (D. Mass. 2011), a litigation where the plaintiffs alleged that a prescription medicine caused suicide and suicide-related injuries, the MDL court dismissed with prejudice more than 160 cases. And in *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, MDL No. 12-2404 DSF (C.D. Cal. 2014), a litigation where the plaintiffs alleged that Nexium caused osteoporosis and fractures, the MDL court granted summary judgment against all of the 269 plaintiffs in the MDL because of their inability to prove general causation. *See id.*, Dkt. [339] at 1 (attached as Ex. 1); *id.*, Dkt. [347] at 1 (attached as Ex. 2).

Plaintiffs seek to confuse the issues by arguing that “none of the MDL cases are presently ripe for consideration of summary judgment” because “[a]n MDL transfer order is not equivalent to an order certifying a class under Fed. R. Civ. P. 23; civil actions do not relinquish their

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<sup>1</sup> *See also In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, MDL No. 2243, Case No. 3:08-cv-00008 (D.N.J. Aug. 1, 2013), Dkt. [2857-2] (Appendix A).

<sup>2</sup> While the cited decision from *Propoxyphene* does not itself dismiss hundreds of cases, it was later applied to other cases and led directly to the dismissal of more than 600 cases from the MDL.

individual nature because they are subject to an MDL transfer.” Pls.’ Br. at 5 & n.6. MDL courts clearly have the power to decide issues common to all cases, including *Daubert* and summary judgment issues. As Plaintiffs recognize, “[p]roof of general causation ... is a prerequisite to recovery by every plaintiff herein.” *Id.* at 13. With the Court’s exclusion of all of Plaintiffs’ experts on general causation in humans, none of the Plaintiffs can establish causation. Thus, Plaintiffs are “unable to prove liability in all cases.” *In re Accutane Prods. Liab.*, MDL No. 1626, Case No. 8:04-MD-2523 (M.D. Fla. 2007), Dkt. [616] at 1 (attached as Ex. 3), *aff’d* No. 07-13883 (11th Cir. August 26, 2008) (attached as Ex. 4).

While Plaintiffs also argue that “product liability plaintiffs are not bound by the results of an MDL common issues adjudication in which they were not parties,” Pls.’ Br. at 5-6 n.6, Defendants are not seeking to bind non-parties. By definition, each individual Plaintiff in this MDL *is* a party and is bound by the *Daubert* rulings made in this MDL Court. All Plaintiffs in this MDL were subject to the *Daubert* proceedings, made their best arguments, and received adverse decisions on general causation. As discussed in greater detail below, Plaintiffs’ further assertion that, in the absence of general causation evidence, “each of the individual plaintiffs in MDL 2342 is entitled to present case-specific expert testimony that supports the contention that Zolof caused his or her specific birth defect” fails as a matter of law. Pls.’ Br. at 6 n.6.

**B. When Evidence of General Causation Is Excluded as Unreliable Under *Daubert*, Summary Judgment Is Required**

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56. The “plain language” of Rule 56 “mandates the entry of summary judgment ... against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *accord State Farm Fire & Cas. Co. v. Holmes Prods.*, 165 F. App’x 182, 187 (3d Cir. 2006). A “failure of proof concerning an

essential element of the nonmoving party's case necessarily renders all other facts immaterial.” *Celotex*, 477 U.S. at 323.

Plaintiffs cannot establish general causation as a matter of law because they lack admissible and sufficient expert testimony that Zolof is a cause of birth defects or PPHN in humans. General causation “is a fundamental element of each” of Plaintiffs’ claims. *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996), *aff’d*, 118 F.3d 1577 (3d Cir. 1997); *see also Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1475 (D.V.I. 1994) (Giles, J., sitting by designation), *aff’d*, 46 F.3d 1120 (3d Cir. 1994).<sup>3</sup> Expert testimony is required to establish general causation. *Rutigliano*, 929 F. Supp. at 783; *Wade-Greaux*, 874 F. Supp. at 1475. Plaintiffs cannot establish general causation because this Court has excluded all of their experts as to general causation in humans under Fed. R. Evid. 702. Where, as here, “expert opinion evidence regarding causation is inadmissible ... summary judgment must be granted to defendants.” *Rutigliano*, 929 F. Supp. at 783; *accord Wade-Greaux*, 874 F. Supp. at 1475. “[A]bsent an admissible general causation opinion, Plaintiffs’ claims necessarily fail and Pfizer’s motion for summary judgment must be granted.” *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 956 (D. Minn. 2009); *see also Raskin*, 125 F.3d at 65-67. Indeed, Plaintiffs concede that “[p]roof of general causation – that exposure to Zolof was capable of causing plaintiffs’ injuries – is a prerequisite to recovery by every plaintiff herein.” Pls.’ Br. at 13.

Courts routinely grant summary judgment on a plaintiff’s failure to pass the *Daubert* threshold on general causation in personal injury cases alleging serious injuries. *E.g.*, *Goldstein v. Centocor, Inc.*, 310 F. App’x 331, 332-33 (11th Cir. 2009); *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254-55 (2d Cir. 2005); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884-86 (10th Cir. 2005). The decision to dismiss is not discretionary. “Without the expert testimony, Wells cannot prove general causation – and judgment *must* be entered for GSK.” *Wells v. SmithKline Beecham*

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<sup>3</sup> This is hornbook tort law. *E.g.*, Keeton *et al.*, *Prosser and Keeton on Torts*, § 41 (5th ed. 1984).

*Corp.*, 601 F.3d 375, 381 (5th Cir. 2010) (emphasis added); *see also Leake v. United States*, 843 F. Supp. 2d 554, 564-65 (E.D. Pa. 2011) (similar).

For example, in *Wade-Greaux*, a decision affirmed by the Third Circuit, the plaintiff alleged that her use of a pharmaceutical product caused her child to be born with birth defects. 874 F. Supp. at 1447-48. The plaintiff's experts proffered general causation opinions. *Id.* at 1448. Judge Giles "concluded that the opinions of each of plaintiff's expert witnesses are inadmissible .... I am constrained to conclude that plaintiff has not met her burden ... to produce evidence sufficient to raise a genuine issue of material fact." *Id.* at 1485. Judge Giles thus granted summary judgment to the defendant. *Id.* at 1485-86.

In *Rutigliano*, a case also affirmed by the Third Circuit, the plaintiff claimed that exposure to the defendants' products caused her to develop formaldehyde sensitization, an allegedly severe permanent disability. 929 F. Supp. at 782. The court concluded that the plaintiff's expert "failed to demonstrate" her general causation opinion was "supported by 'good science'" as required by *Daubert* and, thus, precluded the testimony. *Id.* "As this leaves plaintiff without admissible evidence that her alleged injury was caused by defendants' products, the Court will also grant summary judgment in favor of defendants." *Id.*

In *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003), the plaintiff alleged that her ingestion of the defendant's prescription medicine caused her to suffer a stroke. The court excluded the plaintiff's causation expert and held that, given the plaintiff's "failure to produce competent evidence in support of an element she would be required to prove at trial, summary judgment must therefore be granted to [the defendant]." *Id.* at 577.

In *Miller v. Pfizer, Inc.*, 356 F.3d 1326 (10th Cir. 2004), parents alleged that their thirteen-year-old son's ingestion of Zoloft caused him to commit suicide. A week after their son was prescribed Zoloft to treat his depression, he hanged himself. The plaintiff's expert general causation evidence was excluded under *Daubert*; accordingly, the court granted summary judgment to Pfizer because the plaintiffs "had 'no scientific evidence of general causation.'" *Id.* at 1335; *see also id.* at 1331. The Tenth Circuit affirmed. *Id.* at 1336.

In *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347 (N.D. Ga. 2001), *aff'd*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002), two plaintiffs alleged that their use of a prescription medication caused them to suffer strokes and seizures. The court held that in advancing their general causation opinions, Plaintiffs' experts took "scientifically unwarranted 'leaps of faith'" and "have not relied upon reliable scientific methodology." *Id.* at 1370-71. Without expert evidence of general causation, the court concluded that it "must" grant the defendant's motion for summary judgment. *Id.* at 1374.

And in *Amorgianos v. National Railroad Passenger Corp.*, 137 F. Supp. 2d 147 (E.D.N.Y. 2001), *aff'd*, 303 F.3d 256 (2d Cir. 2002), the court held that "[b]ecause plaintiffs have not produced admissible expert evidence on the issue of general causation ... and thus cannot sustain their burden of proof as a matter of law," the defendant was given leave to move for summary judgment. *Id.* at 191. The Second Circuit affirmed. "In the absence of any expert evidence as to general causation ..., defendant was entitled to summary judgment because of plaintiffs' failure to present any admissible evidence in support of their theory of causation." 303 F.3d at 270-71; *see also, e.g., Brooks v. Outboard Marine Corp.*, 234 F.3d 89, 92 (2d Cir. 2000).

Plaintiffs assert that the Court should dismiss without prejudice hundreds of cases to avoid summary judgment. *See* Pls.' Br. at 17. Yet Plaintiffs cannot just walk away from their cases and reserve the right to refile them, while they sit on the eve of a summary judgment motion that would dismiss the cases with prejudice. Summary judgment is, by definition, an adjudication on the merits. There is no such thing as summary judgment without prejudice. "Indeed, the very concept of granting summary judgment without prejudice is internally incoherent." *Rivera v. PNS Stores, Inc.*, 647 F.3d 188, 194 (5th Cir. 2011). Accordingly, when summary judgment is warranted, dismissal without prejudice is not a legitimate alternative, especially in a case such as this where there are binding decisions that they have no experts to prove general causation in humans, an essential element of their claims.

**C. MDL Courts Enter Summary Judgment for Defendants When Plaintiffs Lack Admissible Expert Evidence of General Causation**

The fact that summary judgment is appropriate where there is no admissible or sufficient expert evidence of general causation is equally true in an MDL as it is in any other case. As to products liability MDLs, the Federal Judicial Center instructs, “[u]se *Daubert* hearings to assess the validity of the general scientific principles at issue, as well as the testimony of the proffered experts, and enter summary judgment if the underlying scientific principles are not properly established.” Federal Judicial Center, *Managing Multidistrict Litig. in Products Liability Cases*, at 37 (2011). Under these circumstances, many MDL courts overseeing inventories of personal injury cases have granted summary judgment after a *Daubert* ruling. *E.g., Rodrigues v. Baxter Healthcare Corp.*, 2014 WL 2442558, at \*1-2 (6th Cir. 2014); *In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig.*, 2010 WL 1727807, at \*1-2 (D.S.C. 2010).<sup>4</sup>

For example, in the *Nexium* MDL, decided just a month ago, the MDL court immediately granted summary judgment against all of the plaintiffs in the MDL after finding their general causation evidence inadmissible under *Daubert*. Specifically, Judge Fischer held that the plaintiffs’ general causation expert failed to satisfy *Daubert* because he did not show, with appropriate epidemiological methodology, that Nexium generally is a cause of osteoporosis, osteopenia, and osteoporotic fractures. *See In re Nexium (Esomeprazole) Prods. Liab. Litig.*, MDL No. 12-2404 DSF, 2014 WL 5313871, at \*1, \*4 (C.D. Cal. 2014). The very next day, the MDL court issued an order dismissing all claims on summary judgment. *Id.*, Dkt. [339] at 1 (Ex. 1). One week later, the MDL court entered judgment “against all Plaintiffs” in the MDL. *Id.*, Dkt. [347] at 1 (Ex. 2).

An MDL case where plaintiffs alleged that PPA-containing drugs caused strokes is also instructive. Judge Rothstein issued a *Daubert* ruling that “expert testimony associated with

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<sup>4</sup> See also *In re Rezulin Prods.*, 2004 WL 2884327, at \*4 (S.D.N.Y. 2004); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 294 F. Supp. 2d 667, 675 (E.D. Pa. 2003); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 220 F. Supp. 2d 414, 420 (E.D. Pa. 2002).

seizures, psychoses, injuries occurring more than three days after ingestion of a PPA-containing product, and cardiac injuries [is] inadmissible.” *In re: Phenylpropanolamine (PPA) Products Liab. Litig.*, 289 F. Supp. 2d 1230, 1251 (W.D. Wash. 2003). Based on this *Daubert* ruling, the court dismissed on summary judgment plaintiffs who failed to show ingestion of the PPA-containing drug less than three days before having a stroke. *See In re: Phenylpropanolamine (PPA) Prods. Liab. Litig.*, MDL No. 1407, Case No. 2:02-cv-00893-BJR (W.D. Wash. 2007), Dkt. [51] at 1 (attached as Ex. 5); *In re: Phenylpropanolamine (PPA) Prods. Liab. Litig.*, MDL No. 1407, Case No. 2:03-CV-00606 (W.D. Wash. 2005), Dkt. [33] at 3-4 (attached as Ex. 6).

The MDL court’s *Daubert* and summary judgment decision in *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644 (D.N.J. 2008), is likewise on point. The *Human Tissue* products liability MDL arose from an alleged criminal enterprise to harvest tissue from human corpses without obtaining proper consents and following appropriate regulations. *Id.* at 649. The plaintiffs alleged that their exposure to the processed tissue product caused them to contract infectious or life-threatening diseases such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, cancer, and prion disease. *Id.* at 658. Applying *Daubert*, the court found that “Plaintiffs have failed to provide any reliable evidence to support their claims of general causation with respect to the transmission of HIV, HBV, HCV, cancer, and syphilis.” *Id.* at 690-91. Because the court was left with no admissible expert evidence in support of the plaintiffs’ claims of general causation as to these diseases, the court held that “summary judgment on the issues before the Court is appropriate.” *Id.* at 690.

Similarly, in *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567 (S.D.N.Y. 2006), the plaintiffs alleged that a prescription drug caused them to suffer liver injuries. The court determined that the plaintiffs failed to provide admissible expert evidence of general causation under *Daubert*. “Without the necessary and admissible expert evidence,” the court concluded, “there is no genuine issue of material fact as to causation, and summary judgment is appropriate.” *Id.* at 579.



And in *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950 (D. Minn. 2009), the plaintiffs alleged that a prescription medicine caused them to suffer vision loss. The court excluded the plaintiff's general causation expert under *Daubert*. *Id.* at 956. As the court observed, its *Daubert* decision "effectively ended the current litigation .... [A]bsent an admissible general causation opinion, Plaintiffs' claims necessarily fail and Pfizer's motion for summary judgment must be granted." *Id.*

**D. Without Evidence of General Causation, Specific Causation Is Irrelevant**

"General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." *Knight*, 482 F.3d at 351; *accord Norris*, 397 F.3d at 881. It is axiomatic that specific causation is irrelevant absent admissible evidence of general causation and that Plaintiffs must first establish general causation before the issue of specific causation is even reached. "[A]n agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general." Federal Judicial Center, *Reference Manual on Scientific Evidence* at 611 (3d ed. 2011). Thus, "because the Court has sustained Pfizer's motion to preclude [Plaintiffs' experts] from testifying as to general causation ... the issue of specific causation is for all practical purposes moot." *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1087 (D. Kan. 2002), *aff'd*, 356 F.3d 1326 (10th Cir. 2004).

Courts – including MDL courts – have held that without reliable expert testimony on general causation, "it is unnecessary to consider whether the plaintiff can establish specific causation." *In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 518 (D.S.C. 2010), *aff'd*, 429 F. App'x 249 (4th Cir. 2011) (citation omitted). Numerous cases are in accord:

- "Sequence matters: a plaintiff must establish general causation before moving to specific causation. Without the predicate proof of general causation, the tort claim fails." *Wells*, 601 F.3d at 378.



- “Evidence concerning specific causation in toxic tort cases is admissible only as a follow-up to admissible general-causation evidence.” *Knight*, 482 F.3d at 351 (citing *Raynor v. Merrell Pharm., Inc.*, 104 F.3d 1371 (D.C. Cir. 1997)).
- “Plaintiff must first demonstrate general causation because without general causation, there can be no specific causation.” *Norris*, 397 F.3d at 881.
- “Plaintiff’s case requires expert testimony to satisfy her burden with respect to both general causation and specific causation.” *Wade-Greaux*, 874 F. Supp. 1475.
- “[P]roof of general causation is a necessary predicate for that of specific causation ....” *In re Rezulin*, 441 F. Supp. 2d at 575.
- The “‘issue of specific causation is material ... only if plaintiff can demonstrate general causation.’” *Soldo*, 244 F. Supp. 2d at 525.
- “In a separate order, the Court has granted Defendants’ motion to exclude Plaintiffs’ offered expert testimony on general causation. There is no dispute that Plaintiffs cannot establish their prima facie cases without that evidence.” *In re Nexium*, Dkt. [339] at 1 (Ex. 1).

Thus, under this “well-established rule,” without admissible expert evidence of general causation, Plaintiffs’ claims “cannot survive.” *In re Bausch & Lomb*, 693 F. Supp. 2d at 518.<sup>5</sup>

## **II. THERE IS NO IMPEDIMENT TO SUMMARY JUDGMENT IN THESE CASES**

### **A. There Is No Legal Basis or Practical Reason to Wait Before Deciding Summary Judgment**

Because Defendants are entitled to summary judgment, this Court should not delay in deciding summary judgment. “Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed ‘to secure the just, speedy and inexpensive determination of every action.’” *Celotex*, 477 U.S. at 327 (citation omitted). “Rule 56 must be construed with due regard not only for the rights of persons asserting claims and defenses that are adequately based in fact to have those claims and defenses tried to a jury, but also for the rights of persons opposing such claims

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<sup>5</sup> That some courts address both general and specific causation when ruling on summary judgment does not mean that specific causation must be assessed before summary judgment can be adjudicated. This is because the issues of general and specific causation are sometimes presented to courts simultaneously. Here, in contrast, pursuant to the Court’s Pretrial Orders, there was a staggered approach to the issue of causation. In recognition that general causation was a threshold and case-dispositive question applicable to all cases in the MDL, the question of general causation was teed up first.

and defenses to demonstrate in the manner provided by the Rule, prior to trial, that the claims and defenses have no factual basis.” *Id.*

Plaintiffs argue that summary judgment is premature because this Court’s *Daubert* opinions recognized the possibility that Plaintiffs could prove Zolof causes birth defects based on other or future scientific evidence. *See* Pls.’ Br. at 6-7. Yet as the Supreme Court recognized in *Daubert* – which itself was a birth defect case – such an argument is legally untenable because it undermines the law’s “project of reaching a quick, final, and binding legal judgment.” 509 U.S. at 597. As courts have frequently recognized when resolving *Daubert* issues – including those that arise in birth defect cases – “the law cannot wait for future scientific investigation and research. We must resolve cases in our courts on the basis of scientific knowledge that is currently available.” *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc); *accord Nat’l Bank of Commerce v. Dow Chemical Co.*, 965 F. Supp. 1490, 1497 (E.D. Ark. 1996) (birth defects), *aff’d*, 133 F.3d 1132 (8th Cir. 1998); *see also Summers v. Missouri Pac. R.R. Sys.*, 897 F. Supp. 533, 542 (E.D. Okla. 1995), *aff’d*, 132 F.3d 599 (10th Cir. 1997); *Bradley v. Brown*, 852 F. Supp. 690, 700 (N.D. Ind. 1994), *aff’d*, 42 F.3d 434 (7th Cir. 1994). Plaintiffs’ argument would negate the finality that parties rely upon and courts recognize as essential.

As the Supreme Court instructed in *Daubert*, “scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly.” 509 U.S. at 597. “Whether the facts, for other non-litigation purposes, continue to evolve is necessarily of little matter to the court. A decision which has the finality of a legal decision must be based upon a discrete and fixed grouping of facts.” *In re TMI Litig. Cases Consol. II*, 911 F. Supp. 775, 829 (M.D. Pa. 1996), *aff’d sub nom. In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000). Even if Plaintiffs could somehow prove causation with other methodologies and potential future evidence, that does not change the fact that Plaintiffs failed to do so here. When a plaintiff fails to prove an essential element of a case, then that case should be dismissed, regardless of whether plaintiff could have made different arguments or used different evidence. In any event, this Court did not state that current scientific studies would

support causation with a different methodology, but rather that the studies supported causation only with the improper methodology of selectively relying only on some studies without looking at the entirety of the literature. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. (Zoloft I)*, 2014 WL 2921648, at \*8-\*12 (E.D. Pa. 2014).

Plaintiffs also argue that summary judgment is premature because they will move for reconsideration of the *Daubert* rulings. *See* Pls.' Br. at 5. But because a schedule has been set for Plaintiffs' motion for reconsideration, there is no reason to delay deciding summary judgment. In any event, Plaintiffs fail to identify any plausible basis for reconsideration, instead suggesting they will rely improperly upon new expert declarations. *See* Pls.' Br. at 5 n.5. Moreover, Plaintiffs proclaim that they have "good arguments to advance at the appellate level," Pls.' Br. at 6, with respect to this Court's *Daubert* rulings. Defendants are confident this Court's rulings are sound and correct and that they will readily pass appellate review. Granting summary judgment will provide the predicate to put Plaintiffs' assertions to the test by allowing them to appeal the *Daubert* rulings.

#### **B. The Presence of Minor Plaintiffs Has No Effect on Summary Judgment**

That Plaintiffs here include children does not alter the summary judgment analysis under Rule 56. Courts have not hesitated to enter summary judgment in cases brought by minors, including in birth defect cases, where plaintiffs did not have admissible expert evidence of general causation. *See, e.g., Wade-Greaux*, 874 F. Supp. at 1447-48, 1485-86 (discussed above).

Courts around the country have entered summary judgment in birth defect cases when plaintiffs lacked admissible expert evidence of general causation. Decisions from the Bendectin litigation are instructive. For example, in *Elkins v. Richardson-Merrell, Inc.*, 842 F. Supp. 996 (M.D. Tenn. 1992), *aff'd*, 8 F.3d 1068 (6th Cir. 1993), it was alleged that the plaintiff minor "was born with severe birth defects because of his mother's ingestion of Bendectin while pregnant." *Id.* at 996. Based on the Sixth Circuit's holding in *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349 (6th Cir. 1992), that the scientific evidence on Bendectin "was not sufficient to allow the jury to decide the issue of causation," the court granted the defendant's motion for

summary judgment. *Elkins*, 842 F. Supp. at 997. Similarly, in *Lee v. Richardson-Merrell, Inc.*, 1992 WL 92750 (6th Cir. 1992), because “the evidence presented by the plaintiffs’ experts fell short of showing that ‘Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy,’” the Sixth Circuit affirmed summary judgment for the defendant. *Id.* at \*2; *see also DeLuca by DeLuca v. Merrell Dow Pharm., Inc.*, 791 F. Supp. 1042, 1059 (D.N.J. 1992), *aff’d*, 6 F.3d 778 (3d Cir. 1993); *Hull by Hull v. Merrell Dow Pharm. Inc.*, 700 F. Supp. 28 (S.D. Fla. 1988).

In *Lynch v. Merrell-Nat’l Labs., Div. of Richardson-Merrell, Inc.*, 830 F.2d 1190 (1st Cir. 1987), another birth defect case, the First Circuit affirmed the exclusion of the plaintiffs’ expert’s general causation opinion, noting that its exclusion “was necessary, admirable, and entirely within the discretion of the court.” *Id.* at 1196. Absent admissible expert testimony on general causation, the First Circuit held, “[s]ummary judgment for the defendant must be affirmed.” *Id.* at 1197 (capitalization omitted). Similarly, in *Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594 (9th Cir. 1996), a birth defect case involving the prescription drug Clomid, the court affirmed the exclusion of the plaintiff’s causation expert, Dr. Done, and accordingly held that “[s]ummary judgment was appropriate since without Done’s testimony, [the plaintiff] offered no evidence of causation, a necessary element of his personal injury action.” *Id.* at 598. And in *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465 (M.D.N.C. 2006), where the court excluded expert testimony that the thimerosal in the defendant’s vaccine caused autism, the court held that “[b]ecause Plaintiffs cannot prove causation,” summary judgment “is also granted.” *Id.* at 479; *see also, e.g., Frischhertz v. SmithKline Beecham Corp.*, 2012 WL 6697124, at \*6-\*7 (E.D. La. 2012).

### **C. Summary Judgment Cannot Be Avoided Based On *In Vivo* and *In Vitro* Data**

Although the Court – drawing a distinction between “the sufficiency of the evidence [and] the admissibility of the testimony,” *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. (Zoloft II)*, 2014 WL 3943916, at \*13 (E.D. Pa. 2014) – did not exclude the biological mechanism opinions of Drs. Cabrera, Levin, and Sadler based on *in vitro* and *in vivo* research,

those opinions are insufficient as a matter of law to establish an essential element of Plaintiffs' claims: general causation in humans. *See, e.g., Raynor*, 104 F.3d at 1375-76; *Wade-Greaux*, 874 F. Supp. at 1451, 1453, 1483. In cases where experts have opined that a prescription drug could cause birth defects on the basis of *in vivo* animal studies, *in vitro* studies, and the study of "analogous" chemicals, the First Circuit and the District of Columbia Circuit have each explained that "[s]tudies of this sort, singly or in combination, do not have the capability of proving causation in human beings" in the absence of confirmatory epidemiological data. *Lynch*, 830 F.2d at 1194; *accord Raynor*, 104 F.3d at 1376. The Sixth Circuit has ruled similarly, finding such evidence to be insufficient, and affirming summary judgment. *See Turpin*, 959 F.2d at 1350, 1360-61. Where, as here, the proffered evidence is insufficient, summary judgment is warranted. *See Daubert*, 509 U.S. at 596 (citing *Turpin*).

### **CONCLUSION**

For the foregoing reasons, this Court should grant Defendants' motion for summary judgment.

Dated: New York, New York  
November 4, 2014

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**CERTIFICATE OF SERVICE**

I hereby certify that on November 4, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

Dated: New York, New York  
November 4, 2014

/s/ Mark S. Cheffo  
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